



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/852,020	05/06/97	MARUYAMA	

HM31/0803
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FRIEBE, S. EXAMINER

1645 ART UNIT PAPER NUMBER

DATE MAILED: 08/03/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/852,020

Applicant(s)
Maruyama et al.

Examiner
Scott D. Priebe, Ph.D.

Group Art Unit
1632



☒ Responsive to communication(s) filed on Jun 29, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 30-56 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 30-56 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The amendment filed 6/29/98 has been entered. Claims 1-29 have been cancelled and claims 30-56 have been added.

Specification

The disclosure is objected to because of the following informalities: The address for the ATCC has changed, pages 133-134 should be amended to provide the new address:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-56 are rejected under 35 U.S.C. 112 for the reasons of record as applied to claims 1-3, 6-8, 11-12, 15-20, and 22-29 in the Office action of 10/23/97, first paragraph, because the specification, while being enabling for claims limited to vectors encoding or bacteriophage particles comprising fusions with lambdoid bacteriophage tail polypeptides that are pV, does not

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reasonably provide enablement for embodiments wherein the lambdoid phage tail proteins are other than pV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 6/29/98 have been fully considered but they are not persuasive. The claims have been amended to include fusions with phage head proteins. As with phage tail proteins, the prior art does not provide information as to whether or not fusions of exogenous polypeptides to phage head proteins would interfere with phage head assembly and packaging. The specification provides no working examples of fusions to any phage capsid protein other than pV, nor does it provide any guidance concerning where fusions may be made to any specific phage capsid protein. Rather the specification merely suggests that other capsid proteins may be used to display exogenous polypeptides, which is simply an invitation to experimentation without any predictable success.

It is argued that the specification need not test all embodiments of the invention. However, as set forth in *In re Fisher*, 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and

physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

The guidance provided for the pV protein cannot be extrapolated to any other capsid protein.

Each capsid protein is different both in structure and function, having different structural and functional roles in head and tail assembly and DNA packaging.

Exhibit I, Mikawa et al., is advanced as evidence of enablement for other capsid proteins. However, Mikawa et al. is not prior art and it is not clear that the methods used to obtain phage displaying polypeptides as pD fusions are commensurate with the teachings in the instant disclosure. For example, amino terminal fusions were made between the second and third codons, rather than at or after the first codon (page 22, col. 1). It is noted that the primary author, Y.G. Mikawa, is not a named inventor on the instant application, which suggests that the contribution of Y.G. Mikawa is in addition to the instant disclosure. It is of note that the reference states in the first paragraph of the discussion (page 27) that the ends of pD are not involved in the interaction between pD subunits or between pD and pE subunits, "an important result for which no guarantee existed at the start of this work". As with pV, one cannot extrapolate from pD fusions where to make fusions to other capsid proteins, such that phage assembly is not impaired. Mikawa et al. specifically states that the authors chose pD because it was dispensable provided the genome was less than 82% of wild type in length, a feature not true for the other capsid proteins.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30, 33-34, 36-40 and 43-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,627,024. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace the claimed invention of the '024 patent.

Applicant has stated that a terminal disclaimer will be filed to overcome this rejection.

However, until such time as the terminal disclaimer is filed, the rejection is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

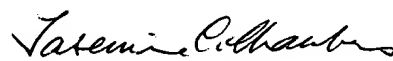
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, Ph.D., can be reached on (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SDP

Scott D. Priebe, Ph.D.
Patent Examiner
Art Unit 1632

July 29, 1998


Jasmine C. Chambers
Supervisory Patent Examiner
Technology Center 1600